

## **REMARKS**

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following commentary.

### **I. Status of the Claims**

No claim amendments are made in this response. Claims 1-24, 36-75 and 87-90 are pending.

### **II. Rejection of Claims under 35 U.S.C. §102(f)**

Claims 1-24, 36-75 and 87-90 are rejected under 35 U.S.C. §102(f) for alleged lack of common inventors in the present application and the parent applications. Applicants respectfully traverse the rejection.

Inventors Rajeev Jain, Jon Swanson, Robert Hontz, John Devane, Kenneth Iain Cumming, Maurice Joseph Anthony Claney and Gary Liversidge are added as co-inventors in the present application. Accordingly, withdrawal of the rejection under 35 U.S.C. §102(f) is respectfully requested.

### **III. Rejection of Claims under 35 U.S.C. §102(e)**

Claims 1-24, 36-75 and 87-90 are rejected under 35 U.S.C. §102(e) for alleged anticipation by U.S. Patent Application Publication No. 2002/0012675 by Jain et al. and by U.S. Patent No. 6,316,029 to Jain et al. Applicants respectfully traverse the each ground of the rejections.

The present application is a continuation-in-part of U.S. Patent Application No. 09/337,675, filed on June 22, 1999, which is continuation-in-part of U.S. Patent Application No. 09/164,351, filed on October 1, 1998, now abandoned. The present application is also a continuation-in-part of U.S. Patent Application No. 10/276,400, filed on January 15, 2003, now

abandoned, which is a national stage application of PCT/US01/15983, filed on May 18, 2001, which claims priority to U.S. Patent Application No. 09/572,961, filed on May 18, 2000, now U.S. Patent No. 6,316,029.

Because the present application claims priority to both the '675 publication and the '029 patent, these references do not qualify as prior art under 35 U.S.C. §102(e) against the present application. Accordingly, Applicants respectfully request withdrawal of the rejection.

**IV. Rejection of Claims under 35 U.S.C. §103(a)**

**A. Liversidge and Stamm**

Claims 1-8, 10-11, 13-15, 17-24, 40-43, 45-50, 52-53, 55-65, 67-68, 70-75 and 87-90 are rejected under 35 U.S.C. §103(a) for allegedly being obvious over U.S. Patent No. 5,145,684 to Liversidge et al. ("Liversidge") in view of PCT Publication No. WO 98/31360 by Stamm et al. ("Stamm"). Applicants respectfully traverse the rejection.

**(i) Lack of a reason to select the claimed active agent**

As the Examiner has acknowledged, Liversidge does not explicitly teach glipizide as the active agent of the claimed composition. In an attempt to remedy the deficiency of the primary reference, the Examiner cites Stamm for the alleged teaching of glipizide as an active agent. More specifically, the Examiner contends: (i) that "glipizide is a well known insoluble drug," (ii) that "the need to improve dissolution and bioavailability of glipizide is well known in the art" and (iii) that Liversidge teaches anti-diabetic agents (Office Action, page 5, lines 2-7).

Liversidge discloses a laundry list of drug categories and illustrative species of drugs without any teaching or suggestion to select an anti-diabetic agent. Rather, Liversidge discloses anti-cancer drugs and steroids in preferred embodiments. See column 3, line 53, through column 4, line 27. Likewise, Stamm describes numerous active agents that are poorly soluble in an

aqueous medium and that would benefit from improved dissolution and bioavailability, such as the drugs listed at page 3, lines 8-17, and at page 5, lines 20-31.

In the absence of any guidance from the cited art to select the particular active agent of the claimed composition, the Examiner has fallen into the trap of hindsight distortion, *i.e.*, breaking the claims down to their component elements, searching for each element in the prior art, and then putting the elements back together using Applicants' claims as a road map. As such, it is only by the improper reliance on this impermissible hindsight that the Examiner identified the specific elements in the references and formulated the combination of the elements as necessary to obtain the claimed composition. See *Ortho-McNeil Pharmaceutical Inc., v. Mylan* (Fed. Cir. 2008) at 10 (“[i]n other words, Mylan’s expert, Dr. Anderson, simply retraced the path of the inventor with hindsight, discounted the number and complexity of the alternatives, and concluded that the invention of topiramate was obvious. Of course this reasoning is always inappropriate for an obviousness test based on the language of Title 35...”).

**(ii) Lack of any reasonable expectation of success**

In the response filed on July 23, 2008, Applicants argued that there is no evidence on the record that one skilled in the art would have a reasonable expectation that a stable nanoparticulate glipizide composition can be made. See pages 24-27.

Similar to the previously cited secondary reference, Kuczynski, Stamm fails to teach a nanoparticulate glipizide composition. Liversidge does not teach or suggest that a stable nanoparticulate glipizide composition can be made either. Rather, Liversidge explicitly states that “not every combination of surface modifier and drug substance provides the desired results [to produce a stable nanoparticulate composition]” (column 7, lines 21-27; columns 14-15, comparative examples). Therefore, the same arguments advanced in the response filed on July 23, 2008 are incorporated herewith by reference. Applicants respectfully urge the Examiner give full consideration to all arguments submitted.

In view of foregoing, the rejection under 35 U.S.C. §103(a) over Liversidge and Stamm should be withdrawn.

**B. Liversidge and Stamm in view of various tertiary references**

Claim 16 is rejected under 35 U.S.C. § 103(a) for alleged obviousness over Liversidge in view of Stamm and GB 2316316 to Baralle et al. ("Baralle"). Applicants respectfully traverse the rejection.

Claims 36-39 are rejected under 35 U.S.C. § 103(a) for alleged obviousness over Liversidge, in view of Stamm and U.S. Patent No. 4,389,397 to Lo et al. ("Lo"). Applicants respectfully traverse the rejection.

Finally, claims 9, 12, 44, 51, 54, 66 and 69 are rejected under 35 U.S.C. § 103(a) for alleged obviousness over Liversidge, in view of Kuczynski and PCT Publication No. WO 98/07414 by Parikh et al. ("Parikh"). Applicants respectfully traverse the rejection.

All of these rejections are based on the common references, Liversidge and Stamm, which are discussed *supra*. Because the rejected claims either depend from a non-obvious base claim or the additional cited art does not compensate for the deficiencies of Liversidge and Stamm, Applicants respectfully request withdrawal of the rejections.

**CONCLUSION**

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to

Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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